

NF Formulas - PhytoPharmica Tyler Encapsulations « Vitaline Formulas

9755 SW Commerce Circle, Suite B2

Wilsonville, OR)

P: 503.582.8386 *

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ENZYMATIC THERADY

INCORPORATED

What Better feels like."

May 11, 2005

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE:

Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
NutriVitamin Enzyme Complex™ with Iron	Multivitamin and Mineral complex formulated for maximum absorption*	Vitamin A (as Natural Beta-Carotene with Mixed Carotenoids, Palmitate), Vitamin C (from Poly-Ascorbate™), Vitamin D (as Cholecalciferol), Vitamin E (as d-Alpha-Tocopheryl Succinate), Vitamin K (as Phytonadione), Thiamine (as Thiamin Hydrochloride), Riboflavin (as Riboflavin 12.6 mg, Riboflavin-5'Phosphate 5.1 mg), Niacin (as Niacinol™), Vitamin B6 (as Pyridoxine HCl 37.5 mg, Pyridoxal-5'-Phosphate 5.1 mg), Folic Acid, Vitamin B12 (as Cyanocobalamin), Biotin, Pantothenic Acid (as Calcium Pantothenate), Calcium (as Calcium Citrate, Malate, Ascorbate), Iron (as Iron Aspartate), Magnesium (as Magnesium Citrate, Ascorbate), Zinc (as Zinc Picolinate, Ascorbate), Selenium (as a Seleniuim Aspartate Complex), Copper (as Copper Aspartate), Manganese (as Manganese Aspartate), Chromium (from GlucoChrome™), Molybdenum (as Molybdenum Aspartate), Potassium (as Potassium Citrate, Ascorbate), Plant Enzymes – Amylase, Protease, Lactase, Lipase, Maltase (Malt Diastase), Sucrase (Invertase), Cellulase, Citrus Bioflavonoids complex, Choline (as Choline Bitartrate), Inositol, Gamma-Oryzanol, Rutin, Pro-Flora™, Lactobacillus rhamnosus, Bifidobacterium bifidum, Lactobacillus acidophilus, Enterococcus faecium, Bifidobacterium infantis, Bifidobacterium longum, Lactobacillus

LET 16195

bulgaricus, lactobacillus plantarum, L-Glutathioine, Reduced, Boron (as Boron Aspartate), Vanadium (as
Vanadium Aspartate)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

Br. KLICUŁ

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date 5-11-05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux Chief Financial Officer



ENZYMATIC THERAPY

INTEGRATIVE THERAPEUTICS INC. NF Formulas • PhytoPharmica
Tyler Encapsulations • Vitaline Formulas

9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582.8386 F: 503.582.0467

ENZYMATIC THERAPY & PHYTOPHARMICA

What Better feels like."

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Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

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PRODUCT	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
NAME		
NutriVitamin	NutriVitamin Enzyme	Vitamin A (as Natural Beta-Carotene with Mixed
Enzyme	Complex is an exclusive	Carotenoids, Palmitate), Vitamin C (from Poly-
Complex™ with	multivitamin and mineral	Ascorbate™), Vitamin D (as Cholecalciferol), Vitamin E
Iron	supplement with highly	(as d-Alpha-Tocopheryl Succinate), Vitamin K (as
	concentrated, synergistic	Phytonadione), Thiamine (as Thiamin Hydrochloride),
	plant enzymes for optimal	Riboflavin (as Riboflavin 12.6 mg, Riboflavin-
	nutritional maintenance.*	5'Phosphate 5.1 mg), Niacin (as Niacinol™), Vitamin
		B6 (as Pyridoxine HCl 37.5 mg, Pyridoxal-5'-Phosphate
		5.1 mg), Folic Acid, Vitamin B12 (as Cyanocobalamin),
		Biotin, Pantothenic Acid (as Calcium Pantothenate),
		Calcium (as Calcium Citrate, Malate, Ascorbate), Iron
		(as Iron Aspartate), Magnesium (as Magnesium
		Citrate, Ascorbate), Zinc (as Zinc Picolinate,
	•	Ascorbate), Selenium (as a Seleniuim Aspartate
		Complex), Copper (as Copper Aspartate), Manganese
		(as Manganese Aspartate), Manganese (as
		Manganese Aspartate), Chromium (from
	1	GlucoChrome™), Molybdenum (as Molybdenum
		Aspartate), Potassium (as Potassium Citrate,
	1	Ascorbate), Plant Enzymes – Amylase, Protease,
		Lactase, Lipase, Maltase (Malt Diastase), Sucrase
		(Invertase), Cellulase, Citrus Bioflavonoids complex,
	,	Choline (as Choline Bitartrate), Inositol, Gamma-
	To proper to the second	Oryzanol , Rutin, Pro-Flora™, Lactobacillus
		rhamnosus, Bifidobacterium bifidum, Lactobacillus
		acidophilus, Enterococcus faecium, Bifidobacterium
		infantis, Bifidobacterium longum, Lactobacillus

,	bulgaricus, lactobacillus plantarum, L-Glutathioine, Reduced, Boron (as Boron Aspartate), Vanadium (as Vanadium Aspartate)
I certify that the information contained in this substantiation that the statements are truthful a	notice is complete and accurate and that Enzymatic Therapy, Inc. has and not misleading.
By:	
Robert C. Doster Title: Senior Vice President of Scientific Aff	airs
Date	
If you have any questions, please contact Robo (920) 406-3608.	ert Doster, Senior Vice President of Scientific Affairs at
Sincerely, Michael P. Devereux Chief Financial Officer	